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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,156	08/07/2001	Rafael A. Sierra	11325-84822	1453

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EXAMINER	
FARAH, AHMED M	

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/924,156	SIERRA ET AL.	
	Examiner	Art Unit	
	Ahmed M Farah	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-15 are again rejected under 35 U.S.C. 102(e) as being anticipated by Anderson U.S. Patent No. 6,600,951 B1.

With respect to claims 1, 7, 1 1 and 15, Anderson '951 discloses methods for treating skin conditions associated with the production of sebum (methods for treating sebaceous gland disorders, see the abstract), comprising the steps of: introducing an exogenous chromophore to sebaceous glands; and irradiating the target sebaceous glands with laser light having a sufficient energy and fluence to disrupt the functions of the sebaceous glands as presently claimed:

> The present invention is based, at least in part, on the discovery that energy activatable materials, such as chromophores, described infra, in combination with an energy source, e.g., photo (light) therapy, can be used to treat sebaceous gland disorders, e.g., eliminate, inhibit, or prevent occurrence or reoccurrence of the skin disorder.
>
> A preferred example of such a sebaceous gland disorder is acne.
>
> The present invention pertains to methods for treating skin disorders associated with sebaceous follicles by **topically applying** an energy activatable material to a section of skin afflicted with a sebaceous gland disorder, wherein

> the material is activated by energy which penetrates outer layers of epidermis. A sufficient amount of the material infiltrates the afflicted section of skin and is exposed to sufficient energy to cause the material to become photochemically or photothermally activated, thereby treating the sebaceous gland disorder. In one embodiment, the sebaceous gland disorder is acne.

Anderson '951, column 1, line 61 to column 2, line 11. As to the wavelength recitation in claims 1 and 15, *Anderson* teaches the preferred wavelength for the treatment is between 600-1200 nm:

> It is highly preferred to use wavelengths of the optical spectrum in which natural skin pigments exhibit weaker absorption (to minimize heating at other sites), and which penetrate well to the anatomic depth of the infundibulum and/or sebaceous glands. The orange, red, and near-infrared wavelength region (600-1200 nm) is therefore most appropriate.

Anderson '951, column 7, line 66 to column 8, line 5. Hence, the wavelength range of *Anderson* embraces and/or overlaps the wavelength range recited in the claims. As to the recitation in claim 15 that 'the target skin is cleaned in a manner to clear the pores,' Anderson teaches the target skin is substantially cleaned:

> Generally, the site of treatment and a major muscle site are cleansed with an alcoholic solution.
>
> ...reactive byproducts can interact with the localized surrounding tissue area such that the tissue is cleansed of unwanted material, e.g., oils, bacteria, viruses, dirt, etc.

Anderson '951, column 15, lines 54-56, and column 6, lines 37-39. Hence, *Anderson* teaches the step of cleaning the target skin as recited in the claim.

With respect to claims 2, 4, 8, and 12, *Anderson* '951 teaches that a chromophore in a lipid suspension is topically applied onto the skin:

> In a one embodiment, liposomes are used to deliver the energy activatable material to the follicle matrix. Liposomes provide site-specific transdermal delivery to the follicle matrix. In this embodiment, the energy activatable material is microencapsulated within the liposome and topically applied to the epidermis of the skin. ...
>
> These liposomal compositions are topically applied to the skin and deliver the encapsulated energy activatable material to the follicle region including the sebaceous gland and infundibulum. ...
>
> The liposomes may be made from natural and synthetic phospholipids, and glycolipids and other **lipids and lipid congeners**; cholesterol, cholesterol derivatives and other cholesterol congeners; charged species which impart a net charge to the membrane; reactive species which can react after liposome formation to link additional molecules to the lysome membrane; and other lipid soluble compounds which have chemical or biological activities.

Anderson '951, column 12, line 57 to column 13, line 25. Hence, Anderson anticipates the recited limitations.

With respect to claim 3, *Anderson* '951 teaches that the lipid suspension comprises water, a pharmaceutical acceptable oil, and at least one surfactant:

> Liquid dosage forms for topical administration of the compounds of the invention include pharmaceutically acceptable emulsions, microemulsions, solutions, creams, lotions, ointments, suspensions and syrups.
>
> The term "cream"' is art recognized and is intended to include semi-solid emulsion systems which contain both an oil and water. Oil in water creams are water miscible and are well absorbed into the skin, Aqueous Cream BP. Water in oil (oily) creams are immiscible with water and, therefore, more difficult to remove from the skin. These creams are emollients, lubricate and moisturize, e.g., Oily Cream BP. Both systems require the addition of either a natural or a synthetic **surfactant** or emulsifier'.

Anderson '951, column 12, lines 3-6, and column 12, lines 29-37. Hence, *Anderson* anticipates the lipid suspension comprises a water, a pharmaceutical acceptable oil, and at least one surfactant recited in the claim.

With respect to claims 5 and 6, *Anderson* '951 teaches the chromophore is selected from the group consisting a dye such as indocyanine green:

> Preferred energy activatable materials include laser sensitive dyes, for example, methylene blue, indocyanine green and those in U.S. Pat. No. 4,651,739, issued Mar. 24, 1987, the entire contents of which are incorporated herein by reference.
>
> Delivery of the energy activatable material, preferably methylene blue or other FDA approved dyes, to the follicle matrix can be achieved by topical application, injection, liposome encapsulation technology, massage, iontophores is or ultrasonic technology, or other means for delivery of compounds into the dermal region of the skin, e.g., pharmaceutically acceptable carriers.

Anderson '951, column 5, line 67 to column 6, line 4., and column 1 1, lines 27-33, respectively.

With respect to claims 13 and 14, Anderson $951 teaches that the chromophore is topically delivered to the target site through a solubilizing carrier selected from the group consisting of sunflower oil, olive oil, and safflower oil:

> a pharmaceutically acceptable material, composition or vehicle, such as a liquid or solid filler, diluent, excipient, solvent or encapsulating material, involved in carrying or transporting a energy activatable material of the present invention within or to the subject ..... some examples of materials which can serve as pharmaceutically acceptable carriers include: ... oils, such as peanut oil. cottonseed oil, safflower oil, sesame oil, olive oil, corn oil and soybean oil;... Preferred carriers include those which are capable of entering a pore by surface action and solvent transport such that the energy activatable material is carried

> into or about the pore, e.g., into the sebaceous gland, to the plug, into the infundibulum and/or into the sebaceous gland and infundibulum.

Anderson '951, column 11, lines 35-64. Hence, *Anderson* anticipates the recited limitations.

With respect to claims 9 and 10, *Anderson* '951 teaches the suitable laser source is selected from the group consisting of an Nd:YAG, alexandrite, flashlamp-pumped, and diode lasers. He further teaches the suitable pulse duration of 0.1-100 msec and fluence of about 5-100 J/cm^2:

> Suitable energy sources include flashlamp based sources and lasers, Nd: YAG, Alexandrite, flash lamp-pumped dyes such as and diodes.
>
> ... the preferred range of pulse and the ideal pulse duration is duration is 0.1-100 mp, about 10-50 ms.
>
> The tolerable fluence for human skin of an optical pulse in this part of the spectrum is about 5-100 J/cm.sup.2, depending on the amount of epidermal melanin and on wavelength.

Anderson '951, column 2, lines 11-13., column 7, lines 59-61; and column 8, lines 14-17. Hence, *Anderson* anticipates the use of diode laser, a pulse duration of about 1-100 msec, and a fluence of about 5-40 J/cm^2 as recited in the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16-19 are again rejected under 35 U.S.C. 103(a) as being unpatentable over *Anderson* '951 in view of Albacarys et al. U. S. Patent No. 6,338,855 B1.

Although, *Anderson* '951, described above, teaches a method for cleaning the target skin with or without solvent (column, 14, lines 61-63), he does not particularly teach the use of glycolic acid solution mixed with a neutralizing agent such as water, bicarbonate, or glytone.

However, Albacarys et al. teach a solution and method for cleaning skin tissue including acne, the skin cleansing solution including a water soluble glycolic acid solution:

> Nonlimiting examples of conditioning agents useful as water soluble conditioning agents include those selected from the group consisting of Specific examples of useful water soluble conditioning agents include materials such as urea; guanidine; glycolic acid and glycolate salts.
>
> The present invention also relates to a method of cleansing and treating the skin or hair with a personal cleansing article of the present invention. These methods comprise the steps of wetting with water a substantially dry, disposable, single use personal cleansing article comprising a water insoluble substrate, a lathering surfactant, and a skin care active component, and contacting the skin or hair with such wetted article.

Albacarys et al. '855, column 41, lines 47-59; column 50, lines 46-53. Also, see the abstract; column 17, lines 15 to column 18, line 17; and column 25, line 50 to column 26, line 18.

Therefore, it would have been obvious to one skilled in the art at the time of the applicant's invention to modify Anderson in view of Albacmys et al. and use a water and/or water soluble glycolic acid solution in order to clean the target site. This would

enhance the treatment by first cleaning the target from unwanted material such as skin oil, dirt, etc. and removing access photosensitive chromophores from the skin area to reduce/eliminate damage to the untargeted surrounding tissues.

Response to Arguments

Applicant's arguments filed on March 30, 2004, have been fully considered but they are not persuasive. The applicant makes the following arguments/remarks:

A. The applicants' representative argues that the "Anderson reference neither teaches nor suggests Applicants' claimed method steps of irradiating target sebaceous glands with laser light for a time sufficient to ***inhibit sebum production***, as required by claims 1 and 15 and claims depending therefrom."

Furthermore, although the applicants' representative admits that Anderson discloses method of treating sebaceous gland disorders, such as acne, to *eliminate*, ***inhibit***, or *prevent* occurrence or reoccur of the skin disorder (see page 7, paragraph 2 of Applicants' remarks), he nevertheless argues that "Anderson does not teach ***inhibiting*** sebum production, as claimed by Applicants."

In response to these arguments and as admitted by the applicants' representative, Anderson clearly teaches a method for treating skin conditions caused by excessive sebum flow produced by sebaceous gland disorders to eliminate, **inhibit** or prevent the skin condition. See col. 5, lines 15-19, and lines 35-37. He further teaches a method of treating sebaceous gland disorders by diminishing, inhibiting,

eradicating, or preventing excess of sebum secretion. See col. 2, lines 37-64; and col. 8, lines 56-61.

As to the recitation "time sufficient to inhibit sebum production" in claims 1 and 15, the examiner's position is that this term is not very definitive to specifically teach the time of irradiation required to cause inhibition of sebum production. Neither the applicants' specification nor the claims teach the irradiation time required to inhibit sebum production. Hence, since the applicants fail to particularly disclose the sufficient time of irradiation, the examiner's position is that Anderson anticipates Applicants' claimed invention.

B. The applicant's representative further argues that the Anderson reference neither teaches nor suggests "use of a laser light of a ***wavelength that is essentially transmitted by the outer layers of human skin***, as required by claims 7 and 11 and claims depending therefrom."

In response to this argument, Anderson teaches that the optical energy for activating the exogenous chromophore penetrates outer layers of the dermis. He further teaches that 'the wavelengths in the visible to near IR, preferably between 600-1200 nm, have the best penetration depth and are therefore best for use to treat sebaceous gland. See col. 2, lines 5-6; col. 7, line 66 to col. 8, line 6; and col. 9, lines 45-49. Therefore, Anderson clearly teaches that the outer layer of the skin transmits the treatment wavelengths as presently claimed.

C. As to the claim rejection under 35 USC 103, although the applicants' representative agrees with the examiner that the reference of Albacarys et al. is directed

to cleansing articles for skin and/or hair, he argues that the reference fails to cure the deficiency of the primary reference, *such as the and light transmission of the skin layer or the step of irradiating a target sebaceous gland with a laser light to inhibit sebum production.*

In response to this argument, the examiner's position is that the primary reference does not have the alleged deficiencies, see the response to arguments A and B above. Furthermore, the sole purpose for incorporating the reference of Albacarys et al. with the primary reference is to show the obviousness for using the cleansing solution recited in the instant claims. Accordingly, the combination of the references renders obvious the applicants' claimed invention.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

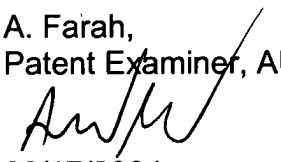
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ahmed M Farah whose telephone number is (703) 305-5787. The examiner can normally be reached on Mon-Thur. 9:30 AM-7:30 PM, and 9:30 AM - 6:30 PM on every other Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M DVorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. Farah,
Patent Examiner, AU 3739



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